# 510(k) Summary

K133009

APR 2 3 2014

## 1. 510(k) Owner's Information:

Name: BMC Medical Co., Ltd.

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Haidian, Beijing 100036, PEOPLE'S REPUBLIC OF CHINA

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Date the summary was prepared [807.92(a)(1)]: September. 17, 2013

## 2. Applicant Device information:

Trade name: BMC-NM Nasal Mask, BMC-NM2 Nasal Mask
BMC-FM Full Face Mask

Common name: Vented Face Mask

Name/classification: Accessory to Non-continuous Ventilator

Product code: BZD

Regulation Number: 21CFR 868.5905

Device Class: II

## 3. Predicate Device

### 3.1 Predicate Device of Nasal Mask BMC-NM and BMC-NM2

**Product name:** ComfortGel™ (K092835) **Manufacturer:** RESPIRONICS

**Product name:** Mirage Activa™ (K030798) **Manufacturer:** Resmed

**Product Code**: BZD

**Intended Use:**

- Mirage ActivaTM Mask (K030798):

Mirage ActivaTM mask is an accessory to a non-continuous ventilator (respirator) intended for single-patient use for adult patients prescribed continuous positive airway pressure (CPAP) and bi-level therapy in hospital, clinic, and home environments.

- ComfortGel™(K092835):

The ComfortGel Blue Nasal Mask is intended to provide an interface for application of CPAP or bi-level therapy to patients. The mask is for single patient use in the home or multi-patient use in the hospital/institutional environment. The mask is to be used by patients (>66lbs/30kg) for whom CPAP or bi-level therapy has been prescribed.

### 3.2 Predicate Device of BMC-FM full face mask

**Product name**: Mirage Quattro (K113127) Manufacturer: Resmed

**Product Code**: BZD

**Intended Use:**

The Mirage Quattro channels airflow noninvasively to a patient from a positive airway pressure device such as a continuous positive airway pressure (CPAP) or bilevel system.

The Mirage Quattro is to be used by adult patients (>66lbs / >30kg) for whom positive airway pressure has been prescribed.

The Mirage Quattro is intended for single patient re-use in the home environment and/or multi-patient reuse in the hospital/ institutional environment.

## 4. Device Description

4.1 BMC-NM and BMC-NM2 Nasal Mask

BMC-NM and BMC-NM2 Nasal Masks are interfaces such that airflow from a positive pressure source is directed to the patient's nose. The masks are held in place with adjustable headgear that straps the mask to the face. BMC-NM and BMC-NM2 Nasal Masks have hard plastic body and softer silicone seal that touches the face and include a pad that rests on the forehead. The seal may inflate once the machine is turned on so the straps do not need to be too tight.

The BMC-NM and BMC-NM2 are safe when used under the conditions and purposes intended as indicated in the labeling provided with the product.

The BMC-NM and BMC-NM2 are prescription devices supplied non-sterile.

4.2 BMC-FM Full Face Mask

BMC-FM full face mask is interfaces such that airflow from a positive pressure source is directed to the patient's mouth and nose. The masks are held in place with adjustable headgear that straps the mask to the face. BMC-FM Full face Mask has plastic body and softer silicone seal that touches the face and include an adjustable pad that rests on the forehead. The seal may inflate once the machine is turned on so the straps do not need to be too tight.

The BMC-FM is safe when used under the conditions and purposes intended as indicated in the labeling provided with the product.

The BMC-FM is prescription device supplied non-sterile.

## 5. Statement of intended use

The BMC-NM, BMC-NM2 Nasal Mask and BMC-FM full face mask channel airflow noninvasively to a patient from a positive airway pressure device such as a continuous positive airway pressure (CPAP) or Bi-level system.

The BMC-NM, BMC-NM2 Nasal Mask and BMC-FM full face mask are:

- To be used by adult patients (>66lbs / >30kg) for whom positive airway pressure has been prescribed.
- Intended for single-patient reuse in home environment and multi-patient re-use in the hospital/institutional environment.

## 6. Technical Comparison to the predicate device

### 6.1 Comparison table1 (Nasal mask to its predicate device)

| Comparison Elements | Applicant Device | | Predicated Device | |
|---|---|---|---|---|
| | **BMC-NM** | **BMC-NM2** | **ComfortGel™ Nasal Mask (K092835)** | **Mirage Activa™ (K030798)** |
| Device name | Nasal mask | Nasal mask | Nasal mask | Nasal mask |
| Classification name | Accessory to Non-continuous Ventilator | Accessory to Non-continuous Ventilator | Accessory to Non-continuous Ventilator | Accessory to Non-continuous Ventilator |
| Product code | BZD | BZD | BZD | BZD |
| **Comparison statement: The applicant devices are substantially equivalent to the predicate devices.** | | | | |
| Intended Use | The BMC-NM and BMC-NM2 Nasal Mask channel airflow noninvasively to a patient from a positive airway pressure device such as a continuous positive airway pressure (CPAP) or Bi-level system.<br>The BMC-NM and BMC-NM2 Nasal Mask are:<br>• To be used by adult patients (>66lbs / >30kg) for whom positive airway pressure has been prescribed.<br>• Intended for single-patient reuse in home environment and multi-patient re-use in the hospital/institutional environment. | | The ComfortGel Blue Nasal Mask is intended to provide an interface for application of CPAP or bi-level therapy to patients. The mask is for single patient use in the home or multi-patient use in the hospital/institutional environment. The mask is to be used by patients (>66lbs/30kg) for whom CPAP or bi-level therapy has been prescribed. | Mirage Activa™ mask is an accessory to a non-continuous ventilator (respirator) intended for single-patient use for adult patients prescribed continuous positive airway pressure (CPAP) and bi-level therapy in hospital, clinic, and home environments. |
| Indications for use | The BMC-NM and BMC-NM2 Nasal Mask channel airflow noninvasively to a patient | | The ComfortGel Blue Nasal Mask is intended to provide an interface | Mirage Activa™ mask is an accessory to a |

| Comparison Elements | Applicant Device | | Predicated Device | |
|---|---|---|---|---|
| | BMC-NM | BMC-NM2 | ComfortGel™ Nasal Mask (K092835) | Mirage Activa™ (K030798) |
| | from a positive airway pressure device such as a continuous positive airway pressure (CPAP) or Bi-level system.<br>The BMC-NM and BMC-NM2 Nasal Mask are:<br>• To be used by adult patients (>66lbs / >30kg) for whom positive airway pressure has been prescribed.<br>• Intended for single-patient reuse in home environment and multi-patient re-use in the hospital/institutional environment. | | for application of CPAP or bi-level therapy to patients. The mask is for single patient use in the home or multi-patient use in the hospital/institutional environment. The mask is to be used by patients (>66lbs/30kg) for whom CPAP or bi-level therapy has been prescribed. | non-continuous ventilator (respirator) intended for single-patient use for adult patients prescribed continuous positive airway pressure (CPAP) and bi-level therapy in hospital, clinic, and home environments. |
| Target population | Adult (>66lbs / >30kg) | | Adult (>66lbs/30kg) | Adult |
| Environment of use | home or hospital/institutional environment | | home or hospital/institutional environment | hospital/clinic and home environment |
| Patient usage type | Single-patient reuse in home environment and multi-patient re-use in the hospital/institutional environment. | | Single-patient reuse in home environment and multi-patient re-use in the hospital/institutional environment. | Single patient reuse |
| Anatomical site | Nose | | Nose | Nose |
| Provided sterile or non-sterile | Not sterile | | Not sterile | Not sterile |
| **Comparison Statement** | **The applicant devices are substantially equivalent to the predicate devices.** | | | |
| Design | Nasal interface and headgear | | Nasal interface and headgear | Nasal interface and headgear |
| Number of mask size | Three-small, medium, and large | | Three-small, medium, and large | Four-small, medium, large, |

| Comparison Elements | | Applicant Device | | Predicated Device | |
|---|---|---|---|---|---|
| | | **BMC-NM** | **BMC-NM2** | **ComfortGel™ Nasal Mask (K092835)** | **Mirage Activa™ (K030798)** |
| | | | | | large and wide |
| Patient circuit connection | | 22mm entrainment valve elbow | | 22mm entrainment valve elbow | 22mm entrainment valve elbow |
| **Comparison Statement** | | **The applicant devices are substantially equivalent to the predicate devices.** | | | |
| **Device Specifications** | Therapy Pressure range | 4 to 30 hPa | | 4 to 30 hPa | 4-20hPa |
| | Intentional leak | 4hPa=19L/min<br>12hPa=34/min<br>20hPa=50L/min<br>30hPa=68L/min | 4hPa=20L/min<br>12hPa=40/min<br>20hPa=51L/min<br>30hPa=72L/min | 4hPa=15L/min<br>12hPa=31/min<br>20hPa=34L/min<br>30hPa=46L/min | 4hPa=19L/min<br>12hPa=34L/min<br>20hPa=45L/min |
| | Dead space (large size) | 145ml | 135ml | 142.6ml | 145ml |
| | Resistance/<br>Pressure Drop | 0.2 hPa at 50L/min<br>0.7 hPa at 100L/min | 0.2 hPa at 50 L/min<br>0.5 hPa at 100 L/min | 0.1 hPa at 50L/min<br>0.25 hPa at 100L/min | 0.3 hPa at 50L/min<br>0.9 hPa at 100L/min |
| | Operating environment | 5 to 40℃<br>10% to 93% relative humidity, non-condensing | | 5 to 40℃<br>15% to 95% relative humidity, non-condensing | 5 to 40℃<br>15% to 95% relative humidity, non-condensing |

| Comparison Elements | | Applicant Device | | Predicated Device | |
|---|---|---|---|---|---|
| | | **BMC-NM** | **BMC-NM2** | **ComfortGel™ Nasal Mask (K092835)** | **Mirage Activa™ (K030798)** |
| | Storage environment | -20 to +55℃<br>10% to 93% relative humidity, non-condensing | | -20 to +60℃<br>up to 95% relative humidity, non-condensing | -20 to +60℃<br>up to 95% relative humidity, non-condensing |
| **Comparison Statement** | | **The applicant devices have similar specifications as the predicate devices.** | | | |
| **Main materials** | | Polycarbonate | | Polycarbonate | Polycarbonate |
| | | Silicon | | Silicon | Silicon |
| | | Nylon &spandex Fabric | | GUrethane gel/EVA<br>Urethane film | "Breathoprene" fabric |
| | | —— | | UBL, Urethane Foam, and Lycra | —— |
| **Comparison Statement** | | **The applicants devices have similar materials with the predicate devices.** | | | |
| **Safety element** | Performance testing | Tested to determine the pressure-flow characteristic, dead space (CO2 re-breathing), and flow impedance. | | Intentional leak, pressure drop, CO2 rebreathing, dead space testing test. | Tested to determine the pressure-flow characteristic, dead space (CO2 re-breathing), and flow impedance. |
| | Clinical testing | None clinical testing needed | | None clinical testing needed | |
| Human factors | | Compliance with FDA guidance | | Compliance with FDA guidance | |
| **Comparison Statement** | | **The applicant devices are substantially equivalent to the predicate devices.** | | | |
| Label and Labeling | | Compliance with FDA guidance | | Compliance with FDA guidance | |

| Comparison Elements | Applicant Device | | Predicated Device | |
|---|---|---|---|---|
| | BMC-NM | BMC-NM2 | ComfortGel™ Nasal Mask (K092835) | Mirage Activa™ (K030798) |
| Comparison Statement | The applicant devices are substantially equivalent to the predicate devices. | | | |

### 6.2 Comparison table 2 (Full face mask to Mirage Quattro (K113127))

| Comparison Elements | Applicant Device | Predicated Device |
|---|---|---|
| | BMC-FM | Mirage Quattro™(K113127) |
| Device name | Full Face Mask | Full Face Mask |
| Classification name | Accessory to Non-continuous Ventilator | Accessory to Non-continuous Ventilator |
| Product code | BZD | BZD |
| **Comparison statement: The applicant device is substantially equivalent to the predicate device.** | | |
| Intended Use | The BMC-FM full face mask channel airflow noninvasively to a patient from a positive airway pressure device such as a continuous positive airway pressure (CPAP) or Bi-level system.<br>The BMC-FM full face mask are:<br>The full face mask is:<br>• To be used by adult patients (>66lbs / >30kg) for whom positive airway pressure has been prescribed.<br>• Intended for single-patient reuse in home environment and multi-patient re-use in the hospital/institutional environment. | The Mirage Quattro channels airflow noninvasively to a patient from a positive airway pressure device such as a continuous positive airway pressure (CPAP) or bilevel system.<br>The Mirage Quattro is to be used by adult patients (>66 lb / 30 kg) for whom positive airway pressure has been prescribed.<br>The Mirage Quattro is intended for single-patient re-use in the home environment and multipatient re-use in the hospital/institutional environment. |

| Comparison Elements | Applicant Device | Predicated Device |
|---|---|---|
| | **BMC-FM** | **Mirage Quattro™(K113127)** |
| Indications for use | The BMC-FM full face mask channels airflow noninvasively to a patient from a positive airway pressure device such as a continuous positive airway pressure (CPAP) or Bi-level system.<br>The BMC-FM full face mask are:<br>The full face mask is:<br>●To be used by adult patients (>66lbs / >30kg) for whom positive airway pressure has been prescribed.<br>● Intended for single-patient reuse in home environment and multi-patient re-use in the hospital/institutional environment. | The Mirage Quattro channels airflow noninvasively to a patient from a positive airway pressure device such as a continuous positive airway pressure (CPAP) or bilevel system.<br>The Mirage Quattro is to be used by adult patients (>66 lb / 30 kg) for whom positive airway pressure has been prescribed.<br>The Mirage Quattro is intended for single-patient re-use in the home environment and multipatient re-use in the hospital/institutional environment. |
| Target population | Adult (>66lbs / >30kg) | Adult (>66lbs/30kg) |
| Environment of use | Home environment and the hospital/institutional environment | Home environment and the hospital/institutional environment |
| Patient usage type | single-patient reuse in home environment and multi-patient re-use in the hospital/institutional environment | single-patient re-use in the home environment and multi-patient re-use in the hospital/institutional environment |
| Anatomical site | Nose and mouth | Nose and mouth |
| Provided sterile or non-sterile | Not sterile | Not sterile |
| **Comparison Statement** | **The applicant device is substantially equivalent to the predicate device.** | |
| Design | face interface and headgear | face interface and headgear |
| Number of mask size | Three-small, medium, and large | Four –Extra small, small, medium, and large |

| Comparison Elements | | Applicant Device | Predicated Device |
|---|---|---|---|
| | | **BMC-FM** | **Mirage Quattro™(K113127)** |
| Patient circuit connection | | 22mm entrainment valve elbow | 22mm entrainment valve elbow |
| **Comparison Statement** | | **The applicant device is substantially equivalent to the predicate device.** | |
| **Device Specifications** | Therapy Pressure range | 4 to 30 hPa | 4 to 40 hPa |
| | Intentional leak | 4 cm H2O =23 L/min<br>8 cm H2O =33 L/min<br>12 cm H2O =43 L/min<br>16 cm H2O =49 L/min<br>20 cm H2O =54 L/min<br>25 cm H2O =63 L/min<br>30 cm H2O =69 L/min | 4 cm H2O =22 L/min<br>8 cm H2O =32 L/min<br>12 cm H2O =41 L/min<br>16 cm H2O =48 L/min<br>20 cm H2O =54 L/min<br>24cm H2O =60L/min<br>28cm H2O =66L/min<br>32cm H2O =72L/min<br>36cm H2O =72L/min<br>38cm H2O =77L/min<br>40cm H2O =82 L/min |
| | Dead space (**large size**) | 246mL | 242 mL |
| | Resistance/<br>Pressure Drop | at 50L/min: 0.2 cm $H_2O$<br>at 100L/min: 0.3 cm $H_2O$ | at 50 L/min: 0.1 cm $H_2O$<br>at 100 L/min: 0.4 cm $H_2O$ |
| | Inspiratory and expiratory resistance (with Anti Asphyxia Valve open to atmosphere) | Inspiration at 50 L/min 1.0 cm H2O<br>Expiration at 50 L/min 1.2 cm H2O | Inspiration at 50 L/min 0.8 cm H2O<br>Expiration at 50 L/min 0.8 cm H2O |
| | Operating environment | 5 to 40℃<br>10% to 93 % relative humidity non-condensing | 5°C to 40°C<br>15% to 95% relative humidity non-condensing |

| Comparison Elements | | Applicant Device | Predicated Device |
|---|---|---|---|
| | | **BMC-FM** | **Mirage Quattro™(K113127)** |
| | Storage and transport environment | -20 to +55℃<br>10% to 93% relative humidity, non-condensing | -20 to +60℃<br>10% to 95% relative humidity, non-condensing |
| **Comparison Statement** | | **The applicant device has similar specifications as the predicate device.** | |
| Materials | | Polycarbonate | Polycarbonate |
| | | Silicon | Silicon |
| | | Nylon &spandex Fabric | Fabric/Nylon |
| **Comparison Statement** | | **The applicants device has similar materials with the predicate devices.** | |
| **Safety element** | Performance testing | Testing according to ISO 17510-2 | Testing according to ISO 17510-2 |
| | Clinical testing | None clinical testing needed | None clinical testing needed |
| **Comparison Statement** | | **The applicant device is substantially equivalent to the predicate device.** | |
| Label and Labeling | | Compliance with FDA guidance | Compliance with FDA guidance |
| **Comparison Statement** | | **The applicant device is substantially equivalent to the predicate device.** | |

## 7. Safety element

### 7.1 Biocompatibility tests

| Model | BMC-NM | BMC-NM2 | BMC-FM | Nasal pillow mask(K112271) |
|---|---|---|---|---|
| Materials | Polycarbonate | | Polycarbonate | Polycarbonate |
| | Silicon | | Silicon | Silicon |
| | Nylon &spandex Fabric | | Nylon &spandex Fabric | Nylon &spandex Fabric |

The materials used in BMC-NM, BMC-NM2 and BMC-FM in this submission are exactly the same as those materials used in nasal pillow mask(K112271) and not through cytotoxicity, sensitization and irritation, which were not performed in this submission.

| Model | BMC-NM | BMC-NM2 | BMC-FM |
|---|---|---|---|
| Contact Type | Tissue contacting | | Tissue contacting |
| duration of contact | Permanent contact | | Permanent contact |

### 7.2 Nonclinical tests

To verify the substantial equivalence claim, the BMC-NM, BMC-NM2 were performance bench tested against the Mirage Activa™ Mask, (K030798) and ComfortGel™ (K092835), the BMC-FM was performance bench tested against the Mirage Quattro (K113127).

The bench testing includes performance test, drop test, damp heat test and disinfection validation test. In the performance tests,it turns out that the passive exhalation port flow, the resistance to flow and the deadspace for both BMC-NM and BMC-NM2 are substantial equivalence with ComfortGel™ Nasal Mask and Mirage Activa™ . In terms of BMC-FM, the passive exhalation port flow, the resistance to flow and the deadspace is substantial equivalence with Mirage Quattro™.

The drop tests show that BMC-NM, BMC-NM2, BMC-FM(Fully assembled and without packaging) and the carton packaging are able to withstand routine handling.

The damp heat tests state that the BMC-NM,BMC-NM2 and BMC-FM withstand damp heat test with no damage to mask components, and

without noticeable degradation of materials or negative impact of component form, fit or function.

The disinfection validation tests show that the BMC-NM, BMC-NM2,BMC-FM may be either thermally or chemically disinfected/reprocessed thirty (30) times with no damage to mask components, and without noticeable degradation of materials or negative impact of component form, fit or function.

In a conclusion, The test reports show that the BMC-NM Nasal Mask,BMC-NM2 Nasal Mask and BMC-FM Full Face Mask are substantially equivalent to the predicate device.

**7.3 Clinical test**

Use of face masks with CPAP or bi-level therapy is proven technology and is well accepted by the medical community. The Bench testing demonstrates that the devices perform in an equivalent manner or that they are substantially equivalent to the predicate devices.

## 8. Conclusion:

The conclusion drawn from these tests is that the performance of the nasal mask BMC-NM, BMC-NM2 and full face mask BMC-FM are substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

April 23, 2014

BMC Medical Co., Ltd.
Ms. Jinjing
5/F Main Building, No.19 Gucheng Street West
Shijingshan, 100043 Beijing,
PEOPLE'S REPUBLIC OF CHINA

Re: K133009
Trade/Device Name: Nasal mask BMC-NM, BMC-NM2 and Full face mask BMC-FM
Regulation Number: 21 CFR 868.5905
Regulation Name: Vented Face Mask
Regulatory Class: Class II
Product Code: BZD
Dated: March 20, 2014
Received: March 24, 2014

Dear Ms. Jinjin:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

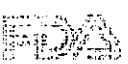
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,




for
Erin I. Keith
Acting Division Director
Division of General Hospital, Respiratory,
Anesthesiology Infectious Control, and Dental
Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

# Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: December 31, 2013
*See PRA Statement on last page.*

510(k) Number *(if known)*
K133009

Device Name
Nasal mask BMC-NM, BMC-NM2 and Full face mask BMC-FM

Indications for Use *(Describe)*
The BMC-NM, BMC-NM2 Nasal Mask and BMC-FM full face mask channel airflow noninvasively to a patient from a positive airway pressure device such as a continuous positive airway pressure (CPAP) or Bi-level system.

The BMC-NM, BMC-NM2 Nasal Mask and BMC-FM full face mask are:
- To be used by adult patients (>66lbs / >30kg) for whom positive airway pressure has been prescribed.
- Intended for single-patient reuse in home environment and multi-patient re-use in the hospital/institutional environment.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

**PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.**

**FOR FDA USE ONLY**

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

James J. Lee
Acting branch chief for Anya Harry MD PhD

Digitally signed by James J. Lee
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